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HAMRE, SCHUMANN, MUELLER & LARSON, P.C.
P.O. BOX 2902
MINNEAPOLIS, MN 55402-0902

EXAMINER	
HAQ, SHAFIQUL	

ART UNIT	PAPER NUMBER
1641	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/586,774	KOSAKA ET AL.	
	Examiner	Art Unit	
	SHAFIQUL HAQ	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 November 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-17* is/are pending in the application.

4a) Of the above claim(s) *14* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-13 and 15-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. Claims 2-17 are pending and claims 2-13 and 15-17 are examined on merits. See the office action of 5/28/09 for withdrawal If non-elected claim 14.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 2-13 and 15-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claim 2 recites "a first step of obtaining a first response value that reflects a protein concentration in the first liquid system" in lines 6-7. The term "the system" lacks antecedent basis as line to recites "liquid sample" not "liquid system".

5. Claim 2 recites "a first step of obtaining a first response value that reflects a protein concentration in the first liquid system, based on coloring of the protein measurement indicator caused by a reaction between the protein and the protein measurement indicator under the influence of a reaction between the creatinine and protein measurement indicator". As described in the specification, creatinine reacts with specific protein measurement indicator (see lines 27-28 on pate 4) but however, specific protein measurement indicator that reacts with creatinine is not recited in the claim and thus it is not clear how protein measurement with all indicator relates to

measurement under the influence of a reaction between the creatinine and the protein measurement indicator wherein the indicator does not react with the creatinine (i.e. not a specific protein measurement indicator that reacts with creatinine).

6. Claim 2 and its dependent claims 3-9, 11-13 and 15-17 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: 1) clear method steps for obtaining a second response value that reflects a creatinine concentration and 2) a clear method steps showing how the elimination of measurement error (corrected response) is calculated and 3) a correlation step as to how the elimination of measurement error is achieved that correlates with the measuring of protein in the liquid sample..

7. Claim 5 and its dependent claims are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. A clear method step(s) of how the corrected response value is calculated.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 2-3, 5, 8, 15, 16 and 17 are again rejected under 35 U.S.C. 102(b) as being anticipated by Messenger *et al* (EP 0909953 A2).

With regard to claims 2 and 5, Messenger *et al* teach a method for measuring an analyte (e.g. albumin) in a sample (e.g. urine that contains creatinine) based on a degree of coloring comprising reacting a first liquid sample with test strip containing reagents causing color change upon reaction with the analyte in the sample (a protein measurement indicator) to determine the uncorrected concentration (i.e. first response value) of the first analyte (e.g. albumin) and then information reflecting a concentration of creatinine (i.e. second response value) in second liquid sample is determined and based on the measured concentration of first liquid sample and the measured concentration of creatinine (i.e. based on the first response value and in consideration of the second response value), influence of creatinine on the protein concentration measurement is then corrected (see paragraph [0006] and claims 1-3).

With regard to claim 3, Messenger *et al* teach subtracting the influence of creatinine (i.e. elimination of the influence of creatinine) by determining a ratio of albumin and creatinine (paragraph [0007]).

With regard to claim 8, Messenger *et al* teach that common assays for measuring concentration of creatinine in second liquid sample include alkaline Jaffe and Benedict-Behre method (paragraph [0002]).

With regard to claim 15, for an indicator for measurement of a protein, use of redox dye or the like is suggested (paragraph [0001]) and a color reaction is measured because colorimetric analysis method is used and since means for measuring the uncorrected concentration of the first analysis object is a test strip, the indicator is considered to be held by a carrier in a dry state (paragraph [0006]).

With regard to claims 16 and 17, Messenger *et al* teach a first analysis object is albumin (paragraph [0006]) and a liquid sample is a body fluid, particularly urine (claims 2 and 9).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claims 4 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Messenger *et al* (EP 0909953 A2).

See the above teaching of Messenger *et al*. The reference teaches measuring uncorrected concentration of protein (e.g. albumin) and measuring concentration of creatinine and the influences thereof are eliminated to make a correction by the concentration of creatinine to measure the concentration of protein in a liquid sample accurately although the method of correction is different.

The method in the reference does not teach in which a calibration curve is determined and a formula is obtained as in the instant claims 4 and 6.

However, the method in which a calibration curve is obtained to make a correction is one of correction methods that are normally carried out by a person skilled in the art. What sort of correction method is to be employed is accordingly determined by a person skilled in the art according to the purpose and a required level of accuracy, and therefore is obvious to one of ordinary skill in the art absent unexpected results.

12. Claims 7 and 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Messenger *et al* (EP 0909953 A2) in view of Waheed *et al* (Analytical Biochemistry 2000).

See the above teaching of Messenger *et al*. The reference teaches measuring uncorrected concentration of protein and measuring concentration of creatinine and the influences thereof are eliminated to make a correction by the concentration of creatinine to measure the concentration of protein in a liquid sample accurately although the method of correction is different.

Messenger *et al* teach immunochromatographic and enzymatic method for measuring of protein (e.g. albumin) in first liquid sample but do not teach a dye binding method for measurement of protein.

Waheed *et al* disclose dye binding method for measurement of proteins (see title and abstract). Waheed *et al* teach that the dyes eosin B and eosin Y provides

instantaneous color development with proteins and is applicable for estimating a wide rage of protein concentrations and the dyes can be used to estimate micro- and sub-microgram quantities of proteins (lines 1-3 of first column and lines 1-18 of second column on page 73).

Therefore, it would be obvious to one of ordinary skill in the art at the time the invention was made to consider the dye binding method of Waheed et al in the method of Messenger *et al* for protein measurement in first protein sample, with the expectation of measuring a wide range of protein concentration with improved sensitivity with a reasonable expectation of success because Waheed *et al* teach that the dyes eosin B and eosin Y provides instantaneous color development with proteins and is applicable for estimating a wide rage of protein concentrations and the dyes can be used to estimate micro- and sub-microgram quantities of proteins.

With regard to claim 11, eosin B and eosin Y are xanthene dyes.

With regard to claim 12, eosin Y and eosin B dye of Waheed *et al* reads on the halogenated xanthene dye of Formula 3 and Formula 6.

13. Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Messenger *et al* (EP 0909953 A2) in view of Waheed *et al* (Analytical Biochemistry 2000) as described above and further in view of Yip *et al* (US 5,385,847).

Messenger *et al* in view of Waheed *et al* teach dye binding method for measurement of proteins but do not teach immunoturbidimetric method or

immunolatex agglutination method for measuring proteins that is less susceptible to creatinine influence.

Yip *et al* describe a method for measurement of creatine and other water-soluble proteins and as a method for measurement of protein, an immunoassay, particularly a coagulation method is employer (see claim 1). Yip et al disclose that immunological methods such as immunoturbidimetry method can measure urinary albumin at a low concentration.

Therefore, it would be obvious to one of ordinary skill in the art to include immunoassay method for measuring albumin because immunological methods can measure urinary albumin at a low concentration (Yip *et al*) and it is easily conceivable by one of ordinary skill in the art that since immunological method involves specific recognition of albumin, the method would be less susceptible to creatinine influence and thus the method would be more accurate to provide albumin concentration in urine.

With regard to claim 10, Yip *et al* teach immunoturbidimetry method and immuno agglutination method for measurement of proteins (Lines 54-58 on column 1 and lines 13-16 on column 3).

Response to argument

14. Applicant's arguments filed 11/30/09 have been fully considered, and are persuasive to overcome some of the rejections under 35 USC 112 second paragraph but

however, Applicants amendment necessitated new ground of rejections under 35 USC 112 second paragraph as described in this office action.

With regard to rejections under 35 USC 102 and 103, Applicants' arguments have been fully considered but are not found persuasive for the reasons of record.

Applicants stated that in the step of obtaining a first response value in claim 2, the first response value that reflects a protein concentration and a reaction between creatinine and the protein measurement indicator is obtained and in the step of obtaining a second response value, the response value that reflects a creatinine concentration is obtained and thus in the method of claim 2, the first response value that reflects concentration of both protein and creatinine and the second response value that reflects creatinine concentration are measured in separate steps, and the steps of calculating a protein concentration in the liquid sample both first and second response values are used to eliminate a measurement error caused by creatinine that is included in the first liquid system and reacts with the protein measurement indication. Applicants argued that in contrast, the reference of Messenger is directed to a method to obtain the ratio of albumin concentration to creatinine concentration of a urine sample, which is known as a creatinine correction value in the art and is used to eliminate an effect of dilution or concentration of urine sample. Applicants urges that the reference Messenger discloses a method to correct the ratio of albumin concentration to creatinine concentration and Messenger however, does not recognize the reaction between creatinine and the protein measurement indicator in the first liquid system, and thus does not recognize a step of obtaining a

first response value that reflects a protein concentration in the first liquid system under influence of a reaction between the creatinine and the protein measurement indicator and the measurement error eliminated in the step of calculating a protein concentration in a liquid sample in claim 2. Consequently, the reference fails to disclose a step of calculating a protein concentration in the liquid sample by using the 1st and second response values for eliminating the measurement error caused by the reaction between creatinine and the protein measurement indicator.

Applicant arguments have been fully considered but are not found persuasive for the reasons of record. Messenger *et al* teach a method for measuring an analyte (e.g. albumin) based on a degree of coloring comprising reacting a first liquid sample with test strip containing reagents causing color change upon reaction with the analyte in the sample (a protein measurement indicator) to determine the uncorrected concentration (i.e. **first response value**) of the first analyte (e.g. albumin) and then information reflecting a concentration of creatinine (i.e. **second response value**) in second liquid sample is determined and based on the measured concentration of first liquid sample and the measured concentration of creatinine (i.e. based on the first response value and in consideration of the second response value), influence of creatinine on the protein concentration measurement is then corrected (see paragraph [0006] and claims 1-3). Although Messenger *et al* do not mention that the first response value is measured "under the influence of a reaction between the creatinine and the protein measurement indicator", the response is in fact measured "under the influence of a reaction between the creatinine and the

protein measurement indicator" because Messenger *et al* teach measuring albumin in an urine sample the contains creatine and thus the influence of creatine would be there in the measurement. The mere recitation of measuring "under the influence of a reaction between the creatinine and the protein measurement indicator" without any further step does not distinguish from measuring in the presence of albumin in the presence of creatine as disclosed by Messenger *et al*. Further, as described above, Messenger et al teach calculating protein concentration (e.g. albumin) in the sample by using the first response value and the second response value, for eliminating a measured error caused by the reaction between the creatinine and the protein measurement indicator in the sample (i.e. by eliminating the influence of creatinine) and the method of claim 2 does not have a distinguishing steps for the elimination process that distinguish it from the correction as described by Messenger et al. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See In re Van Geuns, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Conclusion

15. Applicants' amendment necessitated new ground(s) of rejection presented in this office action. Accordingly, **THIS ACTION IS MADE FINAL**. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

If Applicants should amend the claims, a complete and responsive reply will clearly identify where support can be found in the disclosure for each amendment. Applicant should point to the page and line numbers of the application corresponding to each amendment, and provide any statements that might help to identify support for the claimed invention (e.g., if the amendment is not supported in ipsis verbis, clarification on the record may be helpful). Should Applicants present new claims, Applicants should clearly identify where support can be found in the disclosure.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shafiqul Haq whose telephone number is 571-272-6103. The examiner can normally be reached on 7:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark L. Shibuya can be reached on 571-272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Shafiqul Haq/
Primary Examiner, Art Unit 1641